UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRANCIS FENWICK, EDWARD SAFRAN, STEVE HARDING, MARY WARDRETT, and LINDA YOUNG, Individually and on behalf of all others similarly situated, Plaintiffs, v. RANBAXY PHARMACEUTICALS, INC., RANBAXY LABORATORIES, LTD., RANBAXY LABORATORIES, INC., RANBAXY, INC., RANBAXY USA, OHM LABORATORIES, ABC CORPORATIONS 1-10, and JOHN DOES 1-10, Defendants.	Civil Action No.: 12-CV-07354 (PGS) (DEA)

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR CLASS CERTIFICATION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes, Rules and Regulations

Secondary Authorities

I. INTRODUCTORY STATEMENT

The Class Members in this case seek a refund of the money paid for certain prescription pills that the defendant, Ranbaxy, manufactured and put into the marketplace. The Class Members seek a refund because the Ranbaxy Atorvastatin pills that they purchased were "possibly contaminated with glass particles". Ranbaxy cannot say with certainty whether or not the pills dispensed to Class Members were contaminated but they admit that the pills "possibly contained glass particles." Despite that uncertainty, they refuse to refund the money paid for the Ranbaxy pills.

There should be no dispute that prescription pills which "possibly contain glass particles" are of unacceptable quality, safety, and purity. There should be no dispute that a manufacturer like Ranbaxy should refund the money paid for prescription pills that they put into the marketplace if the manufacturer is uncertain of whether the pills are contaminated with glass particles. American consumers do not have to play "Russian roulette" with the prescription pills that they take for their medical conditions. The uncertainty about the pills the Class Members received makes them substandard and of no value.

In September of 2012, Ranbaxy observed glass particles in the raw materials used to make their Atorvastatin pills. They realized that meant that some of their Ranbaxy Atorvastatin pills "possibly contained glass particles." Ranbaxy eventually had to report to the FDA that they were uncertain of whether or not their Atorvastatin pills contained glass particles. When the FDA learned of the quality problems, they made a public statement that "Americans expect and deserve safe, effective, and high quality medications." The FDA made Ranbaxy recall 41 lots of Ranbaxy Atorvastatin pills that were "possibly contaminated with glass particles." The 41 lots were identified by lot numbers. The pills were also identified by four National Drug Code

numbers ("NDC numbers"), which are unique identifier numbers used to identify prescription pills by manufacturer, dosage, and the number of pills in each bottle in which the pills are initially distributed.

Ranbaxy put 44,530,160 of those recalled pills into the marketplace over a 45 day period before they finally told the pharmacy companies to which they had distributed the pills about the recall. Those 44.5 million substandard pills were mixed into the inventory pools of more than 12,000 retail pharmacy stores and mail order pharmacy companies. Those inventory pools already contained Ranbaxy pills of the exact same type which were not part of the recall but which were identified by the same four NDC numbers. While the 44.5 million recalled pills were being mixed into those inventory pools with identical Ranbaxy pills that were not part of the recall, Ranbaxy pills of that exact type were being dispensed from those inventory pools to Class Members.

During the 45 days before Ranbaxy told the pharmacies about the recall, 960,873 Class Members were dispensed Ranbaxy Atorvastatin pills from those tainted inventory pools. Every one of those pills dispensed to Class Members was the exact same type as the recalled pills, identified by the same four NDC numbers. The majority of prescriptions filled for Class Members were smaller quantities than the original Ranbaxy bottles so the pills were in re-packaged pharmacy bottles that did not state the lot numbers. Moreover, there was no reason to note the lot numbers of the pills dispensed to Class Members because Ranbaxy had not told the pharmacies about the recall. By the time Ranbaxy finally told the pharmacies, the lot numbers of the pills dispensed to Class Members were unknown. The "bad" pills had been mixed with the "good" pills and Ranbaxy did not know whether the prescriptions filled for the Class Members

from the tainted inventory pools included some of the recalled pills. Thus, every one of the pills dispensed to Class Members "possibly contained glass particles."

The glass particles observed in the raw materials used to make Ranbaxy Atorvastatin pills made Ranbaxy uncertain about whether their Atorvastatin pills contained glass particles. That uncertainty about the quality, safety, and purity of the pills was enough for the FDA to make Ranbaxy recall the pills. That same uncertainty exists about the Ranbaxy Atorvastatin pills dispensed to the Class Members because they came from tainted inventory pools and Ranbaxy cannot say if the pills received were of acceptable quality, safety, and purity. The Ranbaxy pills had to be recalled because they "possibly contained glass particles" and the same is true about the pills dispensed to Class Members. Ranbaxy simply does not know. That uncertainty means that both the recalled pills and the pills dispensed to Class Members were of unacceptable quality, safety and purity. Such pills are substandard and worthless.

The final comments in this introductory section are about two anticipated arguments by the defendant in opposition to class certification. The first argument offered by the defendant and its expert is that the Class is overbroad because it includes consumers who did not receive recalled pills. The defendant's argument is flawed because it assumes that the Class definition has to be "consumers who received recalled pills." However, that is not the Class definition nor does it have to be. The Class definition in this case is all consumers who were dispensed Ranbaxy pills from inventory pools that included recalled pills. The plaintiffs acknowledge that every Class Member may not have received some of the recalled pills but that does not defeat class certification because that is not the Class definition. The Class Members seek damages because the pills dispensed to them from tainted inventory pools "possibly contained glass particles" and thus were below the acceptable standards of quality, safety, and purity. We

understand that the defendant disagrees with the merits of the plaintiffs' claims but that disagreement does not defeat class certification. The merits of the claims will be decided later.

The second argument offered in opposition to class certification is that the Class includes "uninjured" people because there is no proof that the recalled pills actually contained glass particles. That argument is flawed because it assumes that the only way that consumers could be damaged is if they "received pills that definitely contained glass particles." However, that is not true. The Class Members were damaged because the pills they received had no value. The uncertainty about the quality, safety, and purity of the Ranbaxy pills renders them worthless. The same level of uncertainty that forced Ranbaxy to recall the pills (i.e., the pills "possibly contained glass particles") applies to the Ranbaxy pills dispensed from those tainted inventory pools to the 960,873 Class Members. Again, the defendant disagrees on the merits of the plaintiffs' claims but that does not defeat class certification. Merits issues are for the trial stage. The question of whether the Class Members will recover at trial remains to be seen but what is known at this time is that the claims of all of the Class Members are identical and the Class should be certified.[1]

II. CLASS DEFINITION AND CLASS CLAIMS

Class Definition

The proposed Class Definition is as follows:

> All consumers who were dispensed Ranbaxy Atorvastatin pills identified by four NDC numbers (66304-827-90; 66304-828-90; 66304-829-90; and 66304-829-05) by certain pharmacies and mail order facilities during specific date ranges. Class Members were dispensed pills from inventory pools that included recalled pills of the exact same type that possibly contained glass particles. The Class Periods are

[1] This Motion for Class Certification requests that three of the five plaintiffs be appointed as Class representatives. The three proposed Class representatives are Edward Safran, Steve Harding, and Linda Young. The other two plaintiffs, Francis Fenwick and Mary Wardrett, have factual and legal differences, which mean that their claims will only be on an individual basis.

the date ranges that those inventory pools included some of the recalled pills. The class excludes any consumers who are known with certainty to have received pills that were not from the recalled lots.[2]

Sub-Classes for Management Purposes

There are nine companies that dispensed the Ranbaxy pills to Class Members. Seven of the companies are retail pharmacy companies and the other two companies are mail order pharmacy companies. Sub-classes will be used for management purposes to organize the Class Members by the company that dispensed the pills to them. The sub-classes for management purposes will also facilitate notice to the Class Members and the processing of their claims using the information and data from the specific company that dispensed the Ranbaxy pills to each Class Member.

Class Claims

The Class Members are consumers who were dispensed pills by certain retail pharmacies or mail order pharmacies during certain date ranges when the inventory pools of the pharmacies included identical pills that were recalled because they "possibly contained glass particles." The Class Members received Ranbaxy atorvastatin pills identified by four NDC numbers (66304-827-90; 66304-828-90; 66304-829-90; and 66304-829-05).

The Class claims are that the Ranbaxy pills dispensed to Class Members were substandard because Ranbaxy cannot tell Class Members if the pills they received satisfied the

[2] If more detail is deemed necessary, an alternative Class definition is:
All consumers who were dispensed Ranbaxy Atorvastatin pills identified by four NDC numbers (66304-827-90; 66304-828-90; 66304-829-90; and 66304-829-05) from a list of specified stores of seven retail pharmacy companies or from a list of specified dispensing facilities of two mail order pharmacy companies during specific date ranges. Ranbaxy recalled 41 lots of pills identified by those four NDC numbers because of possible contamination with glass particles. Class Members were dispensed pills from inventory pools that included some of the recalled pills. The Class Periods are the date ranges that the inventory pools of each of the specified retail pharmacy stores included the recalled pills and the date ranges that the inventory pools of each of the specified mail order dispensing facilities included the recalled pills. The class excludes any consumers who are known with certainty to have received pills that were not from the recalled lots.

standards for quality, safety, and purity. Ranbaxy's uncertainty about the quality, safety, and purity of the pills the Class Members received is the same reason that the FDA made Ranbaxy recall the 41 lots of their Atorvastatin pills. Ranbaxy placed the pills dispensed to the Class Members into the marketplace and they are responsible for the quality, safety, and purity of the pills. The Class claims include that Ranbaxy's uncertainty about the pills they put into the marketplace constitutes a breach of the implied warranty of merchantability and a breach of express warranty. The Class claims also include that the defendant's refusal to refund the money paid for the substandard pills results in the defendant being unjustly enriched.[3] (A copy of the Third Amended Complaint is attached as Exhibit "1".)

The defense arguments offered by Ranbaxy are laughable and are offensive to American consumers. Ranbaxy argues that "there is no evidence that any of the pills purchased by proposed Class Members actually contained glass particles." That argument ignores the fact that glass particles were observed in the raw manufacturing materials, which meant that Ranbaxy was uncertain about whether their Atorvastatin pills contained glass particles. That uncertainty is sufficient to render the pills below the acceptable standards for quality, safety, and purity. Ranbaxy also argues that even if the pills did contain glass particles, it "did not have an effect on the efficacy of the pills."[4] Ranbaxy knows that pills which "possibly contain glass particles" are below the applicable standards of quality, safety, and purity regardless of the "efficacy of the pills." We assume that that is the reason that Ranbaxy did not make the "efficacy" argument to the FDA. The FDA ordered Ranbaxy to recall the pills because they "possibly contained glass particles" and the FDA ordered Ranbaxy to destroy any recalled pills that were returned to

[3] While it may not be legally binding, it is certainly noteworthy that the defendant gave full refunds or credits to the companies that returned some of the recalled pills but they chose not to give refunds to consumers. Ranbaxy was concerned about the backlash and the loss of business if they did not give refunds to their commercial customers but they had no concern whatsoever for the individual consumers.

[4] See defendant's expert report by Bruce Strombom at page 8 for both defense arguments. (Exhibit "2")

Ranbaxy. Despite the absurdity of Ranbaxy's defense arguments, the issues will have to wait for the trial of this class action because they are merits issues and not class certification issues. For now, the fact that Ranbaxy is making those defense arguments as to all of the Class Members just provides additional support for class certification by showing the commonality and the predominance of the factual and legal issues involved in the case.

III. STATEMENT OF FACTS

A. The Timeline for the Contamination of the Ranbaxy Atorvastatin Pills[5]

On September 5, 2012, Ranbaxy employees at their Ohm Laboratories facility in New Jersey observed glass particles in the raw materials used to manufacture Ranbaxy's Atorvastatin pills (Ranbaxy's generic Lipitor). The glass particles were identified as being parts of the glass liners in the reactors used in the manufacturing process for the active pharmaceutical ingredient ("API"). On October 22, 2012, 47 days after Ranbaxy observed glass particles in the API, they finally stopped manufacturing and distributing the API materials from the New Jersey Ohm facility. However, Ranbaxy had already shipped the API materials that were contaminated with glass particles to their manufacturing facility in Mohali, India, where it was incorporated into their prescription Atorvastatin pills. Ranbaxy eventually expanded their investigation of the contaminated API and finished Atorvastatin pills to their plant in Mohali, India. However, by the time they did so, millions of Ranbaxy's Atorvastatin pills had been manufactured using the contaminated API and those pills were distributed and sold across America.

On October 24, 2012, 49 days after the glass particles were observed, Ranbaxy first told the FDA about the contamination problems in a Field Alert Report ("FAR").[6] It is worth noting

[5] The factual statements in this section are based on Exhibit 3 and Exhibit 4. Exhibit 3 is a copy of some documents that Ranbaxy filed with the FDA and Exhibit 4 is a copy of Ranbaxy's Drug Recall Notice.

[6] The FDA website states that the "purpose of Field Alert Reports (FARs) is to quickly identify drug products in distribution that pose potential safety threats." (See Exhibit "5".) A drug manufacturer is required by 21 CFR

that the FDA just happened to be at the Ranbaxy facility in Mohali between September 11, 2012 and September 26, 2012 to conduct a different investigation. So, the FDA was at Ranbaxy's Mohali plant for 15 days and yet the defendant did not tell the FDA during that time that the Mohali plaint was using API materials that were contaminated with glass particles. (See Exhibit "6".)

On November 7, 2012, 63 days after the glass particles were first observed, Ranbaxy told the FDA that 40 lots of Ranbaxy Atorvastatin were manufactured in Mohali using the API materials that were contaminated with glass particles. The next day, on November 8th, Ranbaxy added another lot to the list of Ranbaxy Atorvastatin that was made using the contaminated API materials, which completed the list of 41 lots that had to be recalled. (Footnote 7 below discusses the difference between a lot number and an NDC number and how the two types of numbers relate to the recall of the Ranbaxy pills.[7])

On November 9, 2012, 65 days after the glass particles were first observed, Ranbaxy informed the pharmacy companies to which they had shipped pills from the 41 lots that the Ranbaxy Atorvastatin pills that Ranbaxy had put into the marketplace were being recalled because they "possibly contained glass particles". The pharmacy companies quarantined the pills that they could identify and some of the recalled pills were returned by the companies. However,

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314.81(b)(1) to file a Field Alert Report within 3 days of discovering significant problems with distributed drug product. It is unknown why Ranbaxy waited more than a month to file their Field Alert Report with the FDA.

[7] So that the record is complete, we include here a general explanation of lot numbers and NDC numbers for prescription pills in the United States. A lot number identifies exactly when and where a batch of pills was manufactured. Prescription pills of the same type will have different lot numbers if they come from different manufacturing batches. An NDC number is a National Drug Code used as a product identifier for prescription drugs. It is a unique, 10 digit, 3 segment number which identifies the manufacturer, the drug type, the dosage, and the number of pills in the bottle the pills are originally shipped in. Prescription pills of the same type, manufacturer, dosage, and original bottle size will always have the same NDC number. An NDC number can be used to track prescription drugs, including identifying them in the case of product recalls. There were 41 lot numbers and 4 unique NDC numbers involved in the Ranbaxy recall. The 4 NDC numbers identified the recalled pills as being Ranbaxy's generic Lipitor in dosages of 10 mg, 20 mg, or 40 mg, and in bottles of 90 pills or 500 pills. (See Exhibit "7" – Ranbaxy's Press Release.)

millions of the pills had already been mixed into the inventory pools of the companies and many of the pills had already been dispensed to consumers.

Ranbaxy finally posted a press release on its website on November 28th, which was 19 days after they told the pharmacies about the recall and 86 days after they observed the glass particles in the API materials at their facility in New Jersey. (See Exhibit "7") On November 29th, the FDA made a statement, which they updated on November 30th. (See Exhibit "8") The FDA statements to the public said that "Americans expect and deserve safe, effective, and high quality medications." The FDA also said that they would oversee the recall process to correct the quality problems with the Ranbaxy prescription pills.

B. Distribution of the Recalled Pills

Before Ranbaxy told the FDA about the glass particles they observed in the API used to make their Atorvastatin pills, they put 480,425 bottles of the recalled pills into the marketplace. (See Exhibit "9") Those bottles of recalled Ranbaxy pills were not 30 pill bottles as might be expected but instead they were either 90 pill bottles or 500 pill bottles.[8] There were 44,530,160 of the substandard pills put into the marketplace by Ranbaxy. The 500 pill bottles are never sold to consumers but instead they are always repackaged and dispensed in smaller bottles used by local pharmacies, often amber-colored. The 90 pill bottles are also usually repackaged and dispensed in smaller bottles by pharmacies.[9] The information that we have to date from the nine companies that dispensed pills to Class Members shows that the large majority of the Ranbaxy pills dispensed to Class Members were repackaged into 30 pill bottles. The smaller bottles used by pharmacies are labelled with information about the prescription drug but the pharmacies do

[8] Exhibit "10" is a copy of the Ranbaxy bottle labels for the Ranbaxy Atorvastatin pills that were recalled, which are identified by four NDC numbers.

[9] Pharmacies use filler machines or dispenser machines, into which a large number of pills are loaded and then the machines count out the pills to be placed into individual prescription bottles. (See Exhibit "11" - Declaration of Eric Smither of Express Scripts, Inc., for an example of the use of such machines.)

not track the lot numbers of the pills dispensed. As noted above, the pharmacies had no reason to track the lot numbers of the pills dispensed to consumers because Ranbaxy had not told anyone about the contaminated pills. Fortunately, the pharmacies do track the NDC numbers of prescription pills dispensed to consumers. NDC numbers provide the pharmacy with a way to identify the type of pills dispensed to specific customers for record keeping purposes and, if necessary, for a product recall.[10]

The recalled pills were in the marketplace from September 25th to November 9th (45 days) before Ranbaxy notified the pharmacies of the recall. (The consumers were never given notice of the recall.) Ranbaxy shipped the recalled pills to 35 companies to be dispensed to the public. Some of the companies were retail pharmacy companies and some were distributors. There are nine companies that sold pills to Class Members. Seven of those nine companies are retail pharmacy companies and two are mail order pharmacy companies.[11] Those nine companies received 95.4% of the bottles of recalled pills that Ranbaxy put into the marketplace.

During the 45 days before Ranbaxy finally told the pharmacy companies about the recall, the recalled pills were mixed into the inventory pools of pharmacies along with other pills identified by the same four NDC numbers. The pharmacies dispensed pills identified by those four NDC numbers to Class Members from those inventory pools. Of course, during those 45 days, neither the pharmacies nor the consumers were aware that the pills they received "possibly contained glass particles." By the time that Ranbaxy notified the pharmacies of the recall, neither

[10] If a prescription pill is recalled to the consumer level, the NDC number is used to track pills dispensed to consumers since lot numbers are not known, especially for repackaged pills.

[11] The seven retail pharmacy companies are Rite Aid, Peytons/Kroger, CVS, Winn Dixie, Osborn Drugs, Discount Drug Mart, and SuperValu. The two mail order pharmacy companies are Express Scripts and Medco, who subsequently merged.

Ranbaxy nor the pharmacy knew whether the consumers who were dispensed pills from those inventory pools received recalled pills or not.[12]

The prescriptions filled for Class Members could have included recalled pills, which "possibly contained glass particles", or could have been pills of the exact same type that were not part of the recall. All of the pills dispensed were identical. A prescription filled from those inventory pools could include a few of the "bad" pills or many of them. The uncertainty about whether the pills dispensed to consumers from those tainted inventory pools makes all of the pills dispensed substandard. Once the recalled pills were mixed into the inventory pools, any pills dispensed from those inventory pools "possibly contained glass particles." The number of pills that Ranbaxy was "uncertain" about the quality of increased once the recalled pills were mixed into the inventory pools of the pharmacy companies and dispensed to Class Members.

C. The Nine Companies That Dispensed Ranbaxy Pills to Class Members

The seven retail pharmacy companies that dispensed Ranbaxy Atorvastatin pills to the Class Members received the recalled pills from Ranbaxy at one or more of their distribution centers.[13] (See Exhibit "9") Once the recalled pills were received, they were mixed into the inventory pools at those distribution centers. Those inventory pools included other Ranbaxy Atorvastatin pills of the exact same type, identified by the same four NDC numbers. Then, the retail pharmacy companies transferred Ranbaxy Atorvastatin pills identified by those four NDC numbers from the inventory pools at their distribution centers to their retail pharmacy stores for

[12] The lot numbers were printed on the original Ranbaxy bottles, underneath the adhesive label. If a consumer was part of the minority who happened to receive an original Ranbaxy 90 pill bottle with their prescription, the lot number might be discoverable if the adhesive label on the bottle could be peeled back without making the lot number printed underneath the adhesive label illegible. However, consumers were never notified of the recall or of the lot number being hidden under the adhesive label. Ranbaxy eventually posted a press release on their website several weeks after the recall. If a consumer happened to see the Ranbaxy press release, it also did not mention the possibility of finding the lot number under the label glued onto the original 90 pill Ranbaxy bottles.

[13] Peytons/Kroger received pills at 3 of its distribution centers, Rite Aid received pills at 4 of its distribution centers, CVS received pills at 11 of its distribution centers, and the other retail pharmacy companies all received pills at 1 distribution center.

sale to the public. All but one of the retail pharmacy companies tracked the NDC numbers for the Ranbaxy Atorvastatin pills transferred from their distribution centers to their retail pharmacy stores.[14] Once the recalled pills were transferred to the retail stores, they were mixed into the inventory pools at those retail stores, which included other pills of the same type, identified by the same four NDC numbers. The recalled Ranbaxy pills were mixed into the inventory pools of more than 12,000 retail pharmacies. Those retail stores dispensed pills of the same type as the recalled pills, identified by the same four NDC numbers, from their tainted inventory pools to the Class Members. The pills dispensed to Class Members from the inventory pools at those retail stores "possibly contained glass particles."

All seven retail pharmacy companies tracked the NDC numbers of Ranbaxy Atorvastatin pills that their retail stores dispensed to Class Members. The seven retail pharmacy companies know exactly who the Class Members are to whom they dispensed Ranbaxy Atorvastatin pills that "possibly contained glass particles."

Similarly, the two mail order pharmacies that dispensed Ranbaxy Atorvastatin pills to the Class Members received the recalled pills at one or more of their facilities. The mail order pharmacies dispense prescription pills directly to consumers by mail from those facilities. Those mail order pharmacies dispensed pills of the same type as the recalled pills, identified by the same four NDC numbers, from their tainted inventory pools to the Class Members. The pills dispensed from those inventory pools "possibly contained glass particles." The two mail order pharmacies tracked the NDC numbers of Ranbaxy Atorvastatin pills that they dispensed to Class Members. The two mail order pharmacies know exactly who the Class Members are to whom they dispensed Ranbaxy Atorvastatin pills that "possibly contained glass particles."

[14] SuperValu did not locate data tracking NDC numbers of pills transferred from the Distribution Center to their retail stores.

D. The Substandard Pills Dispensed to Class Members

Class Members were dispensed Ranbaxy Atorvastatin pills of the same type and identified by the same four NDC numbers as the recalled pills. Class Members were dispensed those pills out of tainted inventory pools that, without question, included recalled pills. Class Members do not know if they received recalled pills or not. Ranbaxy does not know if Class Members received recalled pills or not. What is known is that Ranbaxy placed pills into the marketplace that "possibly contained glass particles" and that Class Members received pills that "possibly contained glass particles."

The recalled pills that the defendants placed in the marketplace can be tracked from the defendant to the nine companies who dispensed pills to Class Members. The dates that the recalled Ranbaxy Atorvastatin pills were mixed into the inventory pools at the distribution centers of those companies are known. The dates that the retail stores of those companies received pills from the tainted inventory pools of the distribution centers are known. The dates that consumers were dispensed Ranbaxy Atorvastatin pills of the same type as the recalled pills, and identified by the same four NDC numbers, are known. Those consumers are the Class Members in this case.[15]

E. Ranbaxy's "Retail Level Only" Recall

Ranbaxy decided that they would limit the recall to the "retail level only." A "retail level only" recall means that the pharmacies that received the recalled pills could return them and receive a refund from Ranbaxy. Ranbaxy refunded the money to the pharmacies because the pills

[15] Plaintiffs' expert's report is attached as Exhibit "12" and the expert's tables of damages, broken down by the nine companies who dispensed pills to the Class Members, is attached as Exhibit "13". The report discusses the analysis they did of the available information and data. They were able to track the pills into the inventory pools of the distribution centers and over 12,000 retail pharmacy stores and then from those inventory pools to Class Members.

were substandard. Ranbaxy gave refunds for the substandard pills to their corporate customers so that they would continue to do business with Ranbaxy.

Ranbaxy refused to give refunds to consumers who received substandard Ranbaxy Atorvastatin pill.[16] Ranbaxy told consumers that the recall was "retail level only", which meant that consumers would not receive refunds. Of course, Ranbaxy could have given consumers refunds for substandard pills regardless of the "level" of the recall. Instead, they made a business decision not to give refunds to consumers in order to save millions of dollars. To justify the refusal to refund the money, Ranbaxy argued that "there is no evidence that any of the pills purchased by proposed Class Members actually contained glass particles."[17] The defendant also argued that even if the pills did contain glass particles, it "did not have an effect on the efficacy of the pills". It is a travesty and a shame that a company selling generic prescription pills would make such weak arguments to American consumers.

IV. ARGUMENT

A. Ascertainability

The Third Circuit has decided that there is an ascertainability requirement for class actions that will be certified under Rule 23(b)(3). *See*, *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015), as amended (Apr. 28, 2015). "The ascertainability inquiry is two-fold, requiring a plaintiff to show that: (1) the class is 'defined with reference to objective criteria'; and (2) there is 'a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.'" *Id.*, (citing *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d

[16] The defendant produced some pages from call logs for consumers who called about the substandard pills. Some of the call log entries refer to sending a "return kit" to some consumers who would not stop complaining. It is not clear if any refunds were actually paid to those "noisy" consumers but if Ranbaxy can prove that they returned the money paid for the pills to any consumers, those consumers are excluded from the Class.

[17] The defendant makes that argument but it is noteworthy that they did not conduct any tests themselves on the pills that were returned to them to see if they "actually contained glass particles".

349, 355 (3d Cir. 2013)), (citing *Marcus v. BMW of N. Am., LLC,* 687 F.3d 583, 593–94 (3d Cir.2012)). The Third Circuit used the *Byrd* decision to clarify its prior ascertainability rulings. *Byrd*, 784 F.3d at 161 ("there has been apparent confusion in the invocation and application of ascertainability in this Circuit.") The Court tried to clarify the confusion by noting that "[t]he ascertainability requirement consists of nothing more than these two inquiries. And it does not mean that a plaintiff must be able to identify all class members at class certification—instead, a plaintiff need only show that "class members *can* be identified." *Id.* at 163, (citing *Carrera,* 727 F.3d at 308 n. 2 (emphasis added)).

In this case, the ascertainability requirement has been met. The class is "defined with reference to objective criteria" and there is "a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." First, the Class definition is clear and refers to objective criteria to describe class members. Second, plaintiffs have provided an expert report explaining the mechanism for identifying the class members who come within the class definition.

The class definition is consumers who received Ranbaxy Atorvastatin pills identified by four distinct NDC numbers from the inventory pools of specified pharmacies during specific date ranges. The objective criteria is very clear and it functions to separate and identify all consumers who received Ranbaxy Atorvastatin pills from inventory pools that included recalled pills of the same type.

The "reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition" is also very clear. The discovery, investigation, and non-party discovery in the case enables us to track the recalled Ranbaxy pills into the inventory pools of the nine companies which dispensed pills to Class Members. Using the

information and data from those nine companies, we can identify the consumers who were dispensed pills from their inventory pools on dates that those inventory pools were tainted with recalled Ranbaxy pills. The plaintiffs' expert has examined and analyzed the data and information that is available. The expert wrote computer codes to analyze and sort the data and information in order to identify consumers who come within the Class definition. (More specifically, they wrote and used statistical programs to analyze the information and data.) In a nutshell, the expert's methodology uses the relevant dates in the companies' records and sorts through the sales records of more than 12,000 retail pharmacies to "determine whether putative class members fall within the class definition." The methodology identifies: the inventory pools that included recalled pills; the Class Members who were dispensed pills from those tainted inventory pools (specific identities of consumers have been redacted until after the class is certified); the date that the Class Member received the pills; the pharmacy that dispensed the pills; the quantity, dosage, and NDC numbers of the pills dispensed to each Class Member; the amount paid by the Class Member; the amount paid by any third party payors; and the total amount paid for the pills.[18] The expert's methodology was used to determine that there were 960,873 prescriptions filled with Ranbaxy Atorvastatin pills dispensed from tainted inventory pools that included recalled pills. The expert's methodology is a reliable and administratively feasible mechanism under the ascertainability requirement. The expert's methodology is also used to calculate the Class Members' damages under the different measures of damages that will be available at trial for awarding damages.

Thus, the ascertainability requirement has been satisfied in this case.

B. **An Overview of Rule 23 and Related Case Law**

[18] A few of the nine companies have redacted more information than others until the Class is certified, either for privacy reasons or because of business concerns of their own.

Rule 23 of the Federal Rules of Civil Procedure states that one or more members of a class may maintain a class action if the suit satisfies the four prerequisites of subsection (a) and fits within one of the three categories in subsection (b). The U.S. Supreme Court has held that Rule 23 "creates a categorical rule entitling a plaintiff whose suit meets the specified criteria to pursue his claim as a class action." *See*, *Shady Grove Orthopedic Associates v Allstate Ins. Co.*, 130 S. Ct. 1431, 1437 (2010). The Supreme Court flatly rejected arguments that Rule 23 sets "eligibility criteria" under which the Court may or may not allow a class action to proceed, even if all of the rule's criteria are met. *Id.* at 1438 ("The discretion suggested by Rule 23's 'may' is discretion residing in the plaintiff. He may bring his claim in a class action if he wishes.").

When analyzing whether a case satisfies the requirements of Rule 23, "the court may 'consider the substantive elements of the plaintiffs' case in order to envision the form that a trial on those issues would take.'" *Hydrogen Peroxide* 552 F.3d 305, 317 (3d Cir. 2008), (quoting *Newton*, 259 F.3d 154, 166 (3d Cir. 2001)). At the same time, "plaintiffs are not required to conclusively demonstrate the merit of their claims in order to obtain certification as a class, even though doing so will be necessary to ultimately prevail. Rather, they must show that the elements of those claims are 'capable of proof at trial through evidence that is common to the class rather than individual to its members.'" *In re Mercedes-Benz Tele. Aid Contract Litigation*, 257 F.R.D. 46, 55 (D.N.J. 2009) (citing *Hydrogen Peroxide*). Class certification must be granted if "the evidence more likely than not establishes each fact necessary to meet the requirements of Rule 23." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 320 (3d Cir. 2009).

In deciding whether to grant class certification, the court "must consider all relevant evidence and arguments presented by the parties" in order to resolve only those factual and legal disputes that are relevant to Rule 23's class certification requirements. *Hydrogen Peroxide*, 552

F.3d at 307. The Third Circuit has made it clear that the "class certification stage is not the place for a decision on the merits." *Williams v. Jani–King of Philadelphia Inc.,* 837 F.3d 314, 322 (3d Cir. 2016), (citing *Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds,* 568 U.S. 455, 465–66, 133 S. Ct. 1184, 1194–95, 185 L. Ed. 2d 308 (2013)) ("Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage. Merits questions may be considered to the extent—but only to the extent—that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." (citing *Wal–Mart Stores, Inc. v. Dukes,* 131 S. Ct. 2541.)

The Supreme Court has noted that "[c]lass actions serve an important function in our system of civil justice." *Gulf Oil Co. v Bernard*, 452 U.S. 89, 99 (1981). Class actions permit plaintiffs to "vindicate the rights of individuals who otherwise might not consider it worth the candle to embark on litigation in which the optimum result might be more than consumed by the cost." *Deposit Guaranty Nat'l Bank v Roper*, 445 U.S. 326, 338 *reh'g denied*, 446 U.S. 947 (1980).

C. **All Elements Required For Class Certification In This Matter Have Been Satisfied**

Rule 23(a) establishes four prerequisites for the certification of a class action:

> (1) the class is so numerous that joinder of all members is impracticable;
> (2) there are questions of law or fact common to the class;
> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
> (4) the representative parties will fairly and adequately protect the interests of the class.

There is sufficient evidence in this case to establish that all four of those elements have been met. Once the prerequisites of Rule 23(a) are established, the Court must find that the

action satisfies one or more of the three subsections of Rule 23(b). In this case, class certification is requested under Rule 23 (b)(3), which has been satisfied.

1. The Four Prerequisites of Rule 23(a) are Satisfied

(a) Numerosity: Rule 23(a)(1)

Rule 23(a)(1) requires that the class be "so numerous that joinder of all members is impracticable." The focus of the numerosity requirement of Rule 23 is judicial economy. The rule does not set out a precise numerical standard, but presents an impracticability of joinder requirement, of which class size is an inherent consideration. 1 *H. Newberg and A. Conte, Newberg On Class Actions*, §3:11 (5th ed. 2011). The Third Circuit has stated that "no minimum number of plaintiffs is required to maintain a suit as a class action, but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met". *Stewart v. Abraham,* 275 F.3d 220, 226-27 (3d. Cir. 2001). (citing *5 James Wm. Moore et al., Moore's Federal Practice* § 23.22[3][a] (Matthew Bender 3d ed.1999)).

In this case, there are 960,873 Class Members.[19] Accordingly, plaintiffs satisfy the numerosity requirement of Rule 23(a).

(b) Commonality: Rule 23(a)(2)

Rule 23(a)(2) requires that there be "common questions of law or fact among members of the class." The Third Circuit has set a low threshold for satisfying the commonality requirement. *See*, *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.,* 259 F.3d 154, 183 (3d Cir. 2001), as amended (Oct. 16, 2001). The Supreme Court noted in *Wal-Mart Stores, Inc. v. Dukes* that one common question of law or fact is sufficient to satisfy the commonality requirement of Rule

[19] The information and data produced by the pharmacy companies in response to non-party subpoenas show that there were 960,873 prescriptions filled for Class Members. The names of the Class Members were redacted. Since generic Lipitor is a "maintenance drug", some of the 960,873 prescriptions could have been dispensed to the same people during the 45 days that are generally covered in the Class Periods. Having noted that here, in this Memorandum of Law we will refer to the 960,873 prescriptions as involving 960,873 Class Members.

23(a)(2). *Wal-Mart Stores, Inc. v. Dukes,* 564 U.S. 338, 359, 131 S. Ct. 2541, 2556, 180 L. Ed. 2d 374 (2011) ("We quite agree that for purposes of Rule 23(a)(2),'[e]ven a single [common] question' will do.") *See also, In re Warfarin Sodium Antitrust Litig.,* 391 F.3d 516, 527-28 (3d Cir. 2004); *and, In re the Prudential Ins. Co. of Am. Sales Practices Litig.*, 148 F.3d 283, 310 (3d Cir.1998) (The "commonality requirement will be satisfied if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class.") The Third Circuit has noted that "because the [commonality] requirement may be satisfied by a single common issue, it is easily met." *Baby Neal v Casey*, 43 F.3d 48, 56 (3d Cir. 1994), (citing *H. Newberg & A. Conte, 1 Newberg on Class Actions § 3.10, at 3–50 (1992)).*

"Common questions are those which arise from a 'common nucleus of operative facts.'" *Thomas v. SmithKline Beecham Corp.,* 201 F.R.D. 386, 392 (E.D. Pa. 2001); *see also*, *City Select Auto Sales, Inc. v. David Randall Assocs., Inc.,* 296 F.R.D. 299, 314 (D.N.J. 2013). In this case, there are numerous common questions of fact and law. The common facts include the following:

(1) All Class Members were dispensed Ranbaxy Atorvastatin pills identified by one of four NDC numbers, which were the NDC numbers involved in the Ranbaxy recall;
(2) All Class Members were dispensed those Ranbaxy Atorvastatin pills during date ranges when the inventory pools from which their pills were dispensed included recalled pills of the exact same type, identified by the same NDC numbers;
(3) Ranbaxy recalled the Atorvastatin pills because they "possibly contained glass particles";
(4) Ranbaxy does not know whether the recalled pills or the pills dispensed to Class Members contained glass particles;
(5) Thus, all Class Members received Ranbaxy Atorvastatin pills that "possibly contain glass particles"; and
(6) Ranbaxy's recall did not provide Class Members with a refund of the money paid for the Ranbaxy pills they received, which "possibly contained glass particles".

Those common facts show that the Class claims arise from a common nucleus of operative facts; namely, the defendants put substandard prescription pills into the marketplace and Class Members were dispensed identical Ranbaxy Atorvastatin pills from tainted inventory pools that included those substandard pills.

An obvious consequence of the common factual experiences of the class members is that they very same legal questions exist for all of them. In this case, the common questions of law include the following:

(1) Were the Ranbaxy pills dispensed to Class Members substandard because of the uncertainty about whether the pills contained glass particles?
(2) Does the uncertainty about whether the pills dispensed to Class Members contained glass particles mean that the pills did not meet the applicable standards for quality, safety, and purity?
(3) Did the defendant breach the implied warranty of merchantability by putting their prescription pills that "possibly contained glass particles" into the marketplace?
(4) Did the defendant breach the express warranty that their generic Lipitor pills were of the same quality, safety, and purity as the brand name Lipitor when they put their prescription pills that "possibly contained glass particles" into the marketplace?
(5) Was the defendant unjustly enriched by the money received for the substandard Ranbaxy pills dispensed to the Class Members?
(6) Are the Class Members entitled to contractual damages for the Ranbaxy Atorvastatin pills they received because the pills were substandard?
(7) Should damages awarded to the Class Members be based on the "out of pocket" damages methodology or on the "retail value" damages methodology (i.e., the full sales price paid for the prescription pills)?

Those two lists of issues establish that there are numerous questions of fact and law that the Class Members have in common.

The significance of commonality is self-evident: it provides the necessary glue among class members to make adjudicating the case as a class worthwhile. *1 Herbert B. Newberg & Alba Conte, Newberg on Class Actions § 3.01, p. 3–4 (3d ed.1992).* As the Supreme Court noted, class claims must be "capable of classwide resolution—which means that determination

of its truth or falsity will resolve an issue that is central to the validity of each of the claims in one stroke." *Wal–Mart Stores, Inc. v. Dukes,* 564 U.S. 338, 131 S.Ct. 2541, 2545, 180 L.Ed.2d 374 (2011). The common contentions of the Class in this case are certainly capable of classwide resolution.

It is clear that there are numerous common questions of fact or law in this case and, as such, the commonality requirement of Rule 23(a)(2) has been met.

(c) Typicality: Rule 23(a)(3)

The typicality requirement of Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Courts have noted that typicality tends to merge with the concept of commonality. *See*, *Wal-Mart Stores, Inc. v. Dukes,* 564 U.S. at fn. 5; (citing *General Telephone Co.,* 457 U.S. at 158, fn. 13); *and see*, *Baby Neal,* 43 F. 3d at 56. While commonality "looks at the relationship among the class members generally", typicality focuses on "the relationship between the proposed class representative and the rest of the class." *1 W. Rubenstein, Newberg on Class Actions, § 3:26 (5th ed. 2011).*

The Third Circuit has also "set a low threshold" for satisfying the typicality test. See *In re Nat'l Football League Players Concussion Injury Litig.,* 821 F.3d 410, 426–27 (3d Cir.), as amended (May 2, 2016), cert. denied sub nom. *Gilchrist v. Nat'l Football League*, 137 S. Ct. 591, 196 L. Ed. 2d 473 (2016), and cert. denied sub nom. *Armstrong v. Nat'l Football League,* 137 S. Ct. 607, 196 L. Ed. 2d 473 (2016), (citing *Newton*, 259 F.3d at 183). The Court has held that "that the named plaintiffs' claims must merely be "typical, in common-sense terms, of the class, thus suggesting that the incentives of the plaintiffs are aligned with those of the class." *In re Schering Plough Corp. ERISA Litig.,* 589 F.3d 585, 598 (3d Cir. 2009), (citing *Beck,* 457 F.3d at 295–96).

"The typicality requirement is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals." *In re Warfarin Sodium Antitrust Litig.,* 391 F.3d 516, 531 (3d Cir. 2004), and *see, Prudential*, 148 F3d at 311; *see also General Telephone Co. of Southwest v. Falcon*, 457 U.S. 147, 157 n.13 (1982). Typicality exists when the class representative's claims involve similar factual circumstances as the claims of the class members and are based on the same legal theories. *See, In re Schering Plough Corp. ERISA Litig.,* 589 F.3d 585, 598 (3d Cir. 2009). Even factual differences do not render a claim atypical "if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the class members and if it is based on the same legal theory." *In re Schering Plough Corp. ERISA Litig.,* 589 F.3d 585, 598 (3d Cir. 2009), (citing *Baby Neal for & by Kanter v. Casey,* 43 F.3d 48, 58 (3d Cir. 1994)), *see also Beck v. Maximus, Inc.* 457 F.3d 291, 295-96 (3d Cir. 2006) (citing *Baby Neal* for typicality standard).

In this case, the class representatives' claims and the Class Members' claims all arise from an identical set of facts. The class representatives were dispensed Ranbaxy Atorvastatin pills of the same type, identified by one of four NDC numbers. So were the Class Members. The class representatives were dispensed Ranbaxy pills from tainted inventory pools that included identical Ranbaxy pills which had been recalled due to "possible contamination with glass particles." So were the Class Members. Thus, the class representatives and the Class Members were all dispensed Ranbaxy Atorvastatin pills which "possibly contained glass particles."

Likewise, the class representatives and the Class Members have identical legal claims. The class representatives contend that the pills they received did not meet the applicable standards for quality, safety, and purity. The Class Members have the same contentions. The class representatives are asserting claims for breach of implied warranty of merchantability,

breach of express warranty, breach of contract, and unjust enrichment. The Class Members are asserting the same claims. Finally, the class representatives seek a refund of the money paid for the Ranbaxy pills they received because they "possibly contained glass particles" and thus were substandard. The Class Members seek refunds based on the same grounds.

It is clear that the claims of the class representatives are typical of the claims of the Class Members. As such, the class representatives' interests are all aligned with the interests of the Class Members. There are no conflicts or differing interests between the class representatives and the Class Members. The typicality requirement of Rule 23(a)(3) has been satisfied.

(d) Adequacy of Representation: Rule 23(a)(4)

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." This inquiry "assures that the named plaintiffs' claims are not antagonistic to the class and that the attorneys for the class representatives are experienced and qualified to prosecute the claims on behalf of the entire class." *Bing Li v. Aeterna Zentaris, Inc.*, 2018 WL 1147082, at *7 (D.N.J. Feb. 28, 2018), (citing *Beck,* 457 F.3d at 296) (citing *Baby Neal,* 43 F.3d at 55).

Class Representatives

The interests of the Class representatives in this case are more than "sufficiently aligned" with the Class Members' interests. The factual and legal basis for the Class representatives' claims are the same as the Class Members' claims, which gives the Class representatives a strong incentive to protect the interests of absent Class Members. The Class representatives and the Class Members were all dispensed Ranbaxy Atorvastatin pills from tainted inventory pools that included recalled Ranbaxy pills of the same type and NDC numbers. There is uncertainty about whether the Ranbaxy pills they received were "contaminated with glass particles." They all

contend that the Ranbaxy pills they received did not meet the applicable standards for quality, safety, and purity. They all contend that the Ranbaxy pills they received were substandard and worthless. They are all asserting claims for breach of implied warranty of merchantability, breach of express warranty, breach of contract, and unjust enrichment. Finally, they all seek a refund of the money paid for the Ranbaxy pills they received which "possibly contained glass particles." It is undeniable that they all have the same goals in this litigation: to prove that the pills they received were substandard and to recover the money paid for those substandard pills. Thus, the proposed Class representatives have a substantial stake in this litigation and a strong incentive to vigorously pursue their claims. Moreover, they have no claims or interests that conflict with those of the class. Their interests are perfectly aligned with the interests of the Class Members.

The adequacy requirement assures that absent class members, who will be bound by the result, are protected by a vigorous and competent prosecution of the case by someone who shares their interests. *See 1 Newberg On Class Actions*, §3:21 (4th Ed. 2004). In this case, that is undeniable. The class representatives in this case "have no interests antagonistic to those of the Class and they have indicated their willingness to represent the Class." *Varacallo v. Massachusetts Mut. Life Ins. Co.,* 226 F.R.D. 207, 233 (D.N.J. 2005). The plaintiffs understand that they are class representatives and they are committed to representing and protecting the interests of the class. Plaintiffs have gathered and produced information and documents concerning their claims. They have relinquished their privacy by exposing their private records, including their pharmacy records, to the defendant's scrutiny. They have spent countless hours on this case, including interrogatories, discovery responses, lengthy depositions, and other assistance to counsel.

If the defendant chooses to question the class representatives' adequacy to represent the class, the burden is on them. *Varacallo v Massachusetts Mut. Life Ins. Co.*, 226 F.R.D. 207, 233 (D.N.J. 2005) (citing *Prudential Insurance*, 962 F.Supp. 450, 519 (D.N.J. 1997)). ("a party challenging class representation has the burden to prove that the representation is not adequate.") The Courts have also held that "any doubt concerning the adequacy of a class representative should be resolved in favor of certification." *Weikel v Tower Semiconductor, Ltd.*, 183 F.R.D. 377, 394 (D.N.J. 1998). "In most cases, adequate representation presumptions are usually invoked in the absence of contrary evidence by the party opposing the class." *Alba Conte & Herbert Newberg, Newberg On Class Actions*, §7:24 (4th Ed. 2002).

Class Counsel

The adequacy inquiry also "factors in competency and conflicts of class counsel." *Beck*, at 457 F.3d at 296 n.2. It assures that the "attorneys for the class representatives are experienced and qualified to prosecute the claims on behalf of the entire class." *Beck v. Maximus, Inc.*, 457 F.3d 291, 296 (3d Cir. 2006), (citing *Baby Neal,* 43 F.3d at 55). Generally, until the contrary is demonstrated, courts will assume that members of the bar are skilled in their profession and the presumption fairly arises that all members of the bar in good standing are competent. *See* 3 *Newberg On Class Actions*, §7:24 (4th Ed. 2002)). Courts consider whether plaintiff's attorney is qualified, experienced, and able to conduct the litigation. *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 312 (3d Cr. 1998). To this, there is no legitimate dispute.

"Although questions concerning the adequacy of class counsel were traditionally analyzed under the aegis of the adequate representation requirement of Rule 23(a)(4) of the Federal Rules of Civil Procedure, those questions have, since 2003, been governed by Rule

23(g)." *Sheinberg v. Sorensen,* 606 F.3d 130, 132 (3d Cir. 2010) As a result, an analysis of the adequacy of class counsel should include the factors listed in Rule 23(g). The rule instructs the Court to consider: (1) the work counsel has done in identifying or investigating potential claims; (2) counsel's experience in handling class actions and the types of claims asserted; (3) counsel's knowledge of the applicable law; and (4) the resources that counsel will commit to representing the class. When those factors are considered, the plaintiffs in this case are represented by competent and experienced counsel who has substantial experience in class action litigation. This Court, including Your Honor, has appointed plaintiff's counsel as Class Counsel in other cases. A summary description of counsel's experience and the firm's resume is attached as Exhibit "14".

In addition to being qualified and experienced, class counsel has had the resources and the ability to conduct this hotly disputed litigation for more than five years. Plaintiffs' counsel has fought long and hard throughout this litigation. Plaintiffs' counsel has performed extensive work in this litigation, including drafting Complaints, investigating the case and working with potential class representatives, briefing and defeating two separate motions to dismiss, conducting discovery on class certification issues (which included submissions and conferences before the Magistrate Judge on disputed discovery issues), obtaining and reviewing more than 20,000 pages of discovery from defendant, obtaining and reviewing extensive FDA documents, defending the depositions of the five plaintiffs, taking the depositions of the defendant's witnesses, conducting substantial non-party discovery from 35 companies, working with plaintiffs' expert on the case, attending plaintiffs' expert's deposition in Washington, D.C., taking defendant's expert's deposition in Los Angeles, and preparing this Class Certification Motion. Plaintiffs' counsel will continue to prosecute this action zealously on behalf of the

proposed Class after class certification is granted. Plaintiffs' counsel is qualified to serve as Class Counsel under Rule 23(g) and the Third Circuit standard. The adequacy element of Rule 23(a) is satisfied.

In summary, the four prerequisites of Rule 23(a) are all satisfied in this case. Numerosity, commonality, typicality and adequacy have all been established. Next, we will turn to the conditions of Rule 23(b).

2. The Conditions of Rule 23(b)(3) are Met

Once the four prerequisites of Rule 23(a) are satisfied, the plaintiffs in a class action must show that the action can be maintained under one of the three subsections of Rule 23(b). The plaintiffs in this case seek class certification under subsection 23(b)(3).

Rule 23(b)(3) provides that a class action may be maintained if the four prerequisites of Rule 23(a) are satisfied and "the Court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." The "twin requirements of Rule 23(b)(3) are known as predominance and superiority." *In re Hydrogen Peroxide Antitrust Litig.,* 552 F.3d at 310. The Supreme Court noted in the *Amchem* case that the predominance and superiority conditions of Rule 23(b)(3) were added to Rule 23 to cover cases "in which a class action would achieve economies of time, effort, and expense, and promote ... uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." *Amchem,* 521 U.S. 591 at 615, 117 S. Ct. 2231 (quoting the Advisory Committee Notes, Adv. Comm. Notes, 28 U.S.C.App., p. 697.) Class certification in this matter would achieve all of those goals. Predominance and superiority are discussed below.

(a) Common Questions of Law or Fact Predominate

Predominance "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, 1045, 194 L.Ed.2d 124 (2016) (quoting *Amchem,* 521 U.S. 591, 623, 117 S.Ct. 2231, 138 L.Ed. 2d 689 (1997)); see also, *Hydrogen Peroxide*, 552 F.3d at 311. "To evaluate predominance, the Court must determine whether the efficiencies gained by class resolution of the common issues are outweighed by individual issues presented for adjudication." *Varacallo v. Massachusetts Mut. Life Ins. Co.,* 226 F.R.D. 207, 231 (D.N.J. 2005), (citing *Prudential I*, 962 F.Supp. at 511) (citing 1 Newberg § 4.25, at 4–81 to 4–86). Courts have readily held that even a few common issues can satisfy this requirement where their resolution will significantly advance the litigation.

In This Case, There are No "Questions Affecting Only Individual Members"

The predominance analysis weighs common question of law or fact against "questions affecting only individual members." In this case, there are no questions that affect only individual members. The evidence that the Class Members will offer includes records from the defendant, records from the nine pharmacy companies, and FDA standards.

While there are factual differences among the Class Members within the data from the nine companies, they are not "questions affecting only individual members" that would have to be weighed against the common questions of law or fact when analyzing predominance. The factual differences relate to the quantity and the dosage of the Ranbaxy pills they received and relate to the amount of money they paid for the pills. The factual differences in the company records are merely specific factual details of their purchases. For example, each Class Member received one of three dosages: 10 mg, 20 mg, or 40 mg. pills. The dosage received is a factual difference between Class Members but it is not a "question affecting only individual members".

The same is true for different amounts paid for their Ranbaxy pills. The factual differences between Class Members are simple "data points" which are all documented in the computer records of the nine companies that dispensed the Ranbaxy Atorvastatin pills to the Class Members. The different data for the Class Members does not constitute "questions affecting only individual members." To the contrary, the data for each Class Member is of the same type and will be used to resolve the common questions of law and fact that predominate.

Discussion of the Causes of Action and Predominance Issues

"In determining the existence of predominance, the court must first examine the underlying cause of action." *Bing Li v. Aeterna Zentaris, Inc.,* 2018 WL 1147082, at *8 (D.N.J. Feb. 28, 2018) (citing *Newton*, 259 F.3d at 172). The elements of the underlying causes of action strongly influence whether common issues predominate. *Erica P. John Fund, Inc. v. Halliburton Co.,* 563 U.S. 804,810 (2011) *("Halliburton I").* Here, the Class claims are for breach of implied warranty of merchantability, breach of express warranty, breach of contract, and unjust enrichment. Your Honor described the Class claims well in the decision denying the defendant's motion to dismiss, wherein you said "the plaintiffs are only seeking a basic contract remedy of a refund for the pills . . ." (See Exhibit "15" at page 6).

On the breach of implied warranty of merchantability cause of action, the Class Members claim that the Ranbaxy Atorvastatin pills they received were not fit for the ordinary purpose for which they are used and that the pills did not satisfy the applicable standards of quality, safety, and purity. Ranbaxy pills of the exact same type were recalled because Ranbaxy observed glass particles in the manufacturing process and Ranbaxy is uncertain of whether the Class Members' pills contained glass particles or not. There were recalled pills in the inventory pools from which

the Class Members' pills were dispensed and Ranbaxy's uncertainty about the quality, safety, and purity of the Class Members' pills renders them unmerchantable.

On the breach of express warranty claim, the Class Members claim that the Ranbaxy generic Lipitor pills they received were not as promised, i.e., were not the equivalent of brand name Lipitor pills. Drug manufacturers who sell generic drugs to American consumers represent that their generic versions of a brand name drug are of the same quality, safety, and purity (among other things) as the brand name drug. The Class Members claim that the defendant breached those express warranties because the pills they received were not of the same quality, safety, and purity as brand name Lipitor.

On the unjust enrichment claim, the Class Members claim that the uncertainty about the glass particles being in their pills makes the pills substandard and worthless. The defendant's refusal to refund the money paid for the worthless pills results in the defendant being unjustly enriched.

Each of those causes of action involves "questions of law or fact that predominate over any questions affecting only individual members." The class-wide evidence that will be offered to prove those causes of action is discussed below.

"Questions of Law or Fact Common to Class Members that Predominate"

The factual situations of the Class Members are essentially identical and they are pursuing the same legal claims. To provide additional detail, we repeat the following lists of common facts and common questions of law that were noted in the section above on the commonality issue:

Common Facts that Predominate:

(1) All Class Members were dispensed Ranbaxy Atorvastatin pills identified by one of four NDC numbers, which were the NDC numbers involved in the Ranbaxy recall;

(2) All Class Members were dispensed those Ranbaxy Atorvastatin pills during date ranges when the inventory pools from which their pills were dispensed included recalled pills of the exact same type, identified by the same NDC numbers;
(3) Ranbaxy recalled the Atorvastatin pills because they "possibly contained glass particles";
(4) Ranbaxy does not know whether the recalled pills or the pills dispensed to Class Members contained glass particles;
(5) Thus, all Class Members received Ranbaxy Atorvastatin pills that "possibly contain glass particles"; and
(6) Ranbaxy's recall did not provide Class Members with a refund of the money paid for the Ranbaxy pills they received, which "possibly contained glass particles".

Common Questions of Law that Predominate:

(1) Were the Ranbaxy pills dispensed to Class Members substandard because of the uncertainty about whether the pills contained glass particles?
(2) Does the uncertainty about whether the pills dispensed to Class Members contained glass particles mean that the pills did not meet the applicable standards for quality, safety, and purity?
(3) Did the defendant breach the implied warranty of merchantability by putting their prescription pills that "possibly contained glass particles" into the marketplace?
(4) Did the defendant breach the express warranty that their generic Lipitor pills were of the same quality, safety, and purity as the brand name Lipitor when they put their prescription pills that "possibly contained glass particles" into the marketplace?
(5) Was the defendant unjustly enriched by the money received for the substandard Ranbaxy pills dispensed to the Class Members?
(6) Are the Class Members entitled to contractual damages for the Ranbaxy Atorvastatin pills they received because the pills were substandard?
(7) Should damages awarded to the Class Members be based on the "out of pocket" damages methodology or on the "retail value" damages methodology (i.e., the full sales price paid for the prescription pills)?

The critical issue in every Class Member's claim is whether the Ranbaxy pills they received were below standards for quality, safety, and purity. At trial, the evidence on that issue will be identical for all of the Class Members' claims. The plaintiffs will offer the following evidence: (1) the defendant observed glass particles in the API materials used to make their Atorvastatin pills; (2) the contaminated API materials were sent to Ranbaxy's plant in Mohali, India and used to make Ranbaxy Atorvastatin pills; (3) the pills made using the contaminated API materials did not satisfy the standards for quality, safety, and purity; (4) the FDA made Ranbaxy recall those pills because they "possibly contained glass particles"; (5) before the pills

were recalled, millions of the recalled pills were put into the marketplace by Ranbaxy; (6) the recalled pills were mixed into the inventory pools of more than 12,000 retail pharmacies; (7) the Class Members were dispensed Ranbaxy Atorvastatin pills from those tainted inventory pools; and (8) Ranbaxy cannot tell the Class Members whether or not the pills they received contain glass particles. The common evidence will determine whether the defendant is liable for the damages suffered by the Class Members, which is the overriding, common legal question.

The plaintiffs' expert also analyzed the common evidence for the purposes of identifying which consumers are in the Class and to calculate the damages. The expert used the dates that the recalled pills were mixed into the inventory pools of the companies and their stores and the dates that pills were dispensed to consumers in order to identify the Class Members. To calculate damages, the expert used the information and data from those nine pharmacy companies about every Class Member's purchase of the Ranbaxy pills (the quantity, dosage, and NDC number of the pills dispensed as well as the amount paid out of pocket by the Class Member and by any third party payor on the Class Member's behalf). The expert's report discusses his methodology and his calculations of damages. (See Exhibit "12" and Exhibit "13") The plaintiffs' expert calculated aggregate damages for the Class Members whose dispensing companies have already provided all of their necessary data. (See Exhibit "12" and Exhibit "13")[20] The expert will do the same when additional data is provided by the other companies, who have stated that they have the necessary information and will provide it after class is certified. The expert can also determine individual damages for each Class Member using the methodology. Such calculations

[20] The table of damages that the expert prepared for CVS customers was an estimate for settlement purposes, which was made clear to the defendant at the expert's deposition and in our settlement letter. The CVS table notes that it uses average sales prices from Rite Aid's data. As a similar retail chain, the thinking was that the average Rite Aid prices would be close to the CVS prices. The averages were applied to the number of CVS sales of the pills in question, which CVS provided to us. The actual CVS sales data will be provided after class certification and the actual calculations will be done to replace the estimates done for settlement purposes. Peytons/Kroger provided the total amount paid for the prescriptions and will provide the breakdown of what the Class Member paid and what any third-party payor paid after class certification.

would be merely ministerial in nature and will not be plagued by resolution of individual member issues. The Third Circuit has noted that the use of such an expert methodology is often seen since "[t]he predominance inquiry seeks to resolve whether there are "reliable means of proving classwide injury[.]" *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 489 (3d Cir. 2015), (quoting *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244, 252–53 (D.C.Cir.2013)). "This is often done with the assistance of experts." *Reyes v. Netdeposit, LLC*, 802 F.3d at 489 (3d Cir. 2015)

The defendant has raised the same defense arguments as to every Class Member. The defendant argues that there is no proof that the pills actually contained glass and even if they did, the contamination did not affect the pills' efficacy. The defendant also argues that the Class Members are not entitled to any more than their out of pocket damages. The defense arguments apply classwide and further enhance the predominance of common questions. see *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 962 F. Supp. at 512–13.

Finally, legal rulings on issues such as summary judgment, awardable damages, and other issues will apply to all Class Members. Jury charges and the verdict sheet will address issues that apply to all Class Members. The jury verdict deciding the damages to be awarded to Class Members will resolve the claims of all Class Members.

For all three causes of actions, New Jersey law should be applied. New Jersey has the greatest interest and the parties have applied New Jersey law in the litigation. The defendant's headquarters are located in New Jersey and the contamination that led to the recall of the Ranbaxy Atorvastatin occurred at their Ohm Laboratories located in New Jersey. Applying the "most significant relationship" test, New Jersey has the most significant contacts. In a nationwide class action against MBNA, the Third Circuit noted that "what the purported

nationwide class shares in common is a relationship with MBNA." See *Lloyd v. MBNA Am. Bank, N.A.,* 27 F. App'x 82, 84 (3d Cir. 2002) The Court ruled that "[b]ecause Delaware is MBNA's state of incorporation and principal place of business, the forum with the most significant contacts with the class is Delaware." Id. "[F]or a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Phillips Petroleum Co. v. Shutts,* 472 U.S. 797, 818, 105 S. Ct. 2965, 2978, 86 L. Ed. 2d 628 (1985) (citing *Allstate Ins. Co. v. Hague,* 449 U.S. 302 at 312-13; 101 S.Ct. 633 at 639-40; 66 L.Ed.2d 521 (1981)).

In addition to the headquarters and the manufacturing facility where the glass was observed both being in New Jersey, there are many other ties to New Jersey. When the FDA made Ranbaxy recall the pills, the entire recall was conducted and managed from the defendant's New Jersey offices.[21] The defendant reported to the FDA office in New Jersey. Ranbaxy's decision that consumers would not receive a refund or replacement pills as part of the recall was made at their offices in New Jersey. The "promises" to Class Members that the Ranbaxy Atorvastatin was a generic Lipitor, and of the same quality, safety and purity, was made in New Jersey and New Jersey has the greatest interest in addressing the failure of Ranbaxy's Atorvastatin to meet the standard for quality, safety, and purity. See *Elias v. Ungar's Food Prod., Inc.*, 252 F.R.D. 233, 249–51 (D.N.J. 2008) ("A New Jersey business made a promise emanating from New Jersey. An express warranty embodies a promise and New Jersey has an interest in

[21] Thousands of pages of e-mails, documents exchanged with the FDA, and reports to the FDA emanated from the New Jersey offices. The issue is not disputed and so, in the interest of brevity of exhibits, all of those documents will not all be attached to the motion papers.

ensuring its businesses live up to their promises to consumers and provide a remedy if the promise is broken.")

New Jersey has a strong interest in regulating companies located within the State even if the corporation's actions affect consumers outside of the State. See *Dal Ponte v. Am. Mortg. Exp. Corp.*, 2006 WL 2403982, at *4–7 (D.N.J. Aug. 17, 2006) ("New Jersey's interest in regulating its domestic businesses and in deterring fraudulent business practices is especially strong given this state's significant contacts to this litigation." (citing *Gantes,* 145 N.J. at 492–97) ("holding that New Jersey's interest in deterring the manufacture of defective products need not yield to Georgia's interest in compensating its citizens in light of lawsuit's material connection to New Jersey -- manufacturer was a New Jersey corporation and product was manufactured in the state") (*Gantes* was reversed on other grounds); and (citing *D'Agostino v. Johnson & Johnson, Inc.,* 133 N.J. 516, 539–40 (1993))("noting that application of New Jersey's *Pierce* doctrine to wrongful discharge claim by American former employee of Swiss subsidiary of New Jersey corporation was 'not exporting New Jersey employment law so much as applying New Jersey domestic policy ... to a domestic company'").

Also, the parties have applied New Jersey law in the litigation. The defendant applied New Jersey law in their arguments in the Motion to Dismiss the Third Amended Complaint in the case. (See Exhibit "16") The defendant argued that the New Jersey Product Liability Law subsumed the claims and argued that New Jersey breach of warranty law and unjust enrichment law supported a dismissal.[22]

[22] To complete the record, attached as Exhibits "17" and "18" are surveys of state laws for implied warranty and express warranty. There are no material variations that raise concerns or which create conflicts with New Jersey law. As for the unjust enrichment claim, this Court examined the unjust enrichment law of the 50 states and noted that there are minor variations but the differences are not material. See, *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 58 (D.N.J. 2009), opinion clarified, 267 F.R.D. 113 (D.N.J. 2010), opinion modified on reconsideration, No. CIV. 07-2720 DRD, 2010 WL 2976496 (D.N.J. July 22, 2010), (citing *Agostino v. Quest Diagnostics, Inc.*, 256 F.R.D. 437, 463–64, 2009 WL 348898 at *22 (D.N.J.2009)).

In summary, it is clear that "questions of law or fact common to Class Members predominate over any questions affecting only individual members." In fact, there are no "questions affecting only individual members." The predominance requirement has been satisfied.

(b) The Superiority of Class Action Treatment

In addition to predominance, Rule 23(b)(3) also requires that a class action be "superior to other available methods for fairly and efficiently adjudicating of the controversy." Fed. R. Civ. P. 23(b)(3). The superiority factor requires a court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods. *In re Mercedes Benz Tele Aid* 257 F.R.D.at 75; (citing *Georgine,* 83 F.3d at 632)."It is generally recognized that class certification is preferred where 'the recovery being sought by each of the plaintiffs is not sufficiently large to render individualized litigation a realistic possibility.'" *Cannon,* 184 F.R.D. at 546 (quoting *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.,* 174 F.R.D. 332, 351 (D.N.J.1997) (citing *Phillips Petroleum Co. v. Shutts,* 472 U.S. 797, 809 (1985)). A class action would allow both sides "to avoid duplicative expenses and take advantage of economies of scale which they would otherwise lack." *In re DVI Inc. Sec. Litig.,* 249 F.R.D. 196, 218 (E.D. Pa. 2008), aff'd sub nom. *In re DVI, Inc. Sec. Litig.,* 639 F.3d 623 (3d Cir. 2011) Here, the prosecution of this litigation as a class action is the superior method of proceeding with this case.

Rule 23(b)(3) provides the following factors[23] for the Court to consider:

> (A) the interest of class members in individually controlling the prosecution of separate actions;

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[23] The Advisory Committee Notes indicate that the four factors of Rule 23(b)(3) are to be considered when analyzing predominance and superiority. However, they are discussed more often in relation to superiority. In this case, the four factors support a finding of predominance and superiority.

(B) the extent and nature of any litigation concerning the controversy already commenced by class members;
(C) the desirability of concentrating the litigation of the claims in the particular forum; and
(D) the difficulties likely to be encountered in managing a class action.

Here, each of these factors favors certification.

The first factor favors class treatment because the Class Members have no interest in pursuing individual claims against the defendant. While the total amount of the damages for the Class is between $10.8 Million (out of pocket damages) and $37.2 Million (retail value damages), the damages for each Class Member are not significant enough to justify individual litigation. *see In re Gen. Motors Corp. Pick–Up Truck Fuel Tank Prods. Liability Litig.*, 55 F.3d 768, 783–84 (3d Cir. 1995). (A class action allows claims such as these to proceed when each claimant's alleged loss is too small to be economically litigated individually.) The second factor also favors class certification since there is no other litigation pending against the defendant by the proposed Class Members. The third factor also favors certification because it is generally "desirable to litigate similar, related claims in one forum." *Cannon,* 184 F.R.D. at 546 (citing *Phillips Petroleum Co. v Shutts*, 472 U.S. 797, 809 (1985)). The District Court of New Jersey is a desirable forum for these claims against the defendant because there are numerous ties to New Jersey. The fourth factor also favors certification because there is no reason to believe there will be any difficulty in managing this case. "The Court must query not whether there will be any manageability problems, but whether reasonably foreseeable difficulties render some other method of adjudication superior to class certification." *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 962 F. Supp. 450, 524–25 (D.N.J. 1997), aff'd sub nom. *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions,* 148 F.3d 283 (3d Cir. 1998).

Since common questions of law or fact predominate and class action treatment is superior to any other available method for the fair and efficient adjudication of this action, the requirements of Rule 23(b)(3) are satisfied.

V. APPOINTMENT OF CLASS REPRESENTATIVES

The three plaintiffs proposed as Class representatives will fairly and adequately represent the interests of the Class. Thus, Edward Safran, Steve Harding, and Linda Young should be appointed as Class Representatives.

VI. APPOINTMENT OF CLASS COUNSEL

The appointment of Barry J. Gainey, Esq. and his firm, Gainey, McKenna & Egleston, as Class counsel is warranted. They will fairly and adequately represent the interests of the Class as required by Rule 23(g). Thus, Barry J. Gainey, Esq. and his firm, Gainey McKenna & Egleston, should be appointed as Class Counsel.

VII. CONCLUSION

For the foregoing reasons, plaintiffs respectfully request that this matter be certified as a class action under Fed. R. Civ. P. 23(b)(3) on behalf of the Class as defined herein, that Edward Safran, Steve Harding, and Linda Young be appointed as the representatives of the Class, and that Barry Gainey, Esq. and Gainey McKenna & Egleston be appointed as Class Counsel.

Dated: March 23, 2018

Respectfully submitted,

/s/ Barry J. Gainey
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